



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/688,459      | 10/13/2000  | Dirk M. Anderson     | 2852-C              | 1630             |

7590 12/18/2001

Immunex Corporation  
Law Department  
51 University Street  
Seattle, WA 98101

EXAMINER

LAZAR WESLEY, ELIANE M

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/688,459**

Applicant(s)  
**Anderson**

Examiner  
**Eliane Lazar-Wesley**

Art Unit  
**1646**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 36-67 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36, 38-40, 42-44, 46-48, 50-52, 54-56, 58-60, 62-64, 66, and 67 is/are allowed.
- 6) ☒ Claim(s) 37, 41, 45, 49, 53, 57, 61, and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

Art Unit: 1646

### **DETAILED ACTION**

1. The preliminary amendment filed January 12, 2001, has been entered.

Claims 36-67 are under consideration.

#### ***Specification***

The specification is objected to because, in the sequence listing, SEQ ID No:10 corresponds to a nucleic acid, and SEQ ID No:11 corresponds to a protein. However, the specification (see for example at page 5, line 18), recites that the protein has SEQ ID No:10. Applicants are invited to correct the inconsistencies throughout the specification.

#### ***Priority***

2. This application lacks the current status of the prior application. A statement reading "now US Patent 6,242,213." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 37, 41, 45, 49, 53, 57, 61 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

Art Unit: 1646

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are to an isolated DNA molecule encoding a RANK-L polypeptide wherein the polypeptide comprises amino-acids 119 to 294 of SEQ ID No:11 (claim 37). The DNA molecule comprises nucleotides 357 to 884 of SEQ ID No:10 (claim 41).

The specification discloses, at page 5, specific fragments of the murine RANK-L of SEQ ID No:10, these fragments being located at position 139 through 294 (line 18), at position 1 through 139 (line 28), or at position 48 through 139 (line 30). Applicants also recite that the carboxy terminal amino acid can be between amino acids 290 through 294 of SEQ ID No:10. However, the Examiner could not find in the specification as filed, specific support for polypeptides at position 119 to 294 of SEQ ID No:11 (or to a polynucleotide at position 357-884 of SEQ ID No:10 encoding it), and it did not flow from the specification that this polypeptide corresponds to a specific portion (i.e. extracellular or transmembrane domain for example) of the RANK-L polypeptide.

Therefore, this constitutes new matter, and it does not appear that Applicants were in possession of this embodiment at the time the application was filed.

If applicants intended to claim that the polypeptide comprises amino-acids 139 to 294 of SEQ ID No:11, they should amend the claims accordingly

5. The claims are free of the art.

6. Boyle, WO9846751, 22 October 1998, teaches a human osteoprotegerin which is 99.6% identical to the instant RANK-L of SEQ ID No:11. (See sequence comparison, attached). This

Art Unit: 1646

reference has a date of publication that is later than the claimed priority date of the instant application.

7. Claims 36, 38-40, 42-44, 46-48, 50-52, 54-56, 58-60, 62-64, 66-67 are allowable.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

December 14, 2001

*ELW*



LORRAINE SPECTOR  
PRIMARY EXAMINER